

510(k) SUMMARY
SureSkin® THIN Hydrocolloid Wound Dressing

K960404

1. DATE PREPARED

January 25, 1996

2. SUBMITTER

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3. CONTACT

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4. DEVICE NAME

SureSkin® THIN Hydrocolloid Wound Dressing

5. DEVICE CLASSIFICATION

Wound Dressings have not been finally classified by FDA.
[Proposed Class I (21 CFR 878.4022)]
Product Code: 79 MGP

6. DEVICE DESCRIPTION AND COMPARISON TO PREDICATE PRODUCTS

The SureSkin® THIN Hydrocolloid Wound Dressing manufactured by Euromed A/S is a wound dressing indicated for the management of dry to lightly exudating dermal ulcers, post-operative wounds, and superficial wounds and abrasions. It is composed of a hydrocolloid material which is in contact with the wound, and an occlusive polyurethane

film backing. The dressing is similar in design, function, materials, and intended use to other hydrocolloid/occlusive dressings currently in commercial distribution, e.g., *DuoDERM* Extra Thin Flexible Hydrocolloid Dressing.

Determination of substantial equivalence for this product was based on descriptive information about the design, materials, and intended use of the device. Biocompatibility testing was performed on the device material in conformance with Tripartite and ISO 10993 recommendations. Results of all biocompatibility tests demonstrated that the device is suitable for its intended use.